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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,771	07/13/2001	Bettina Mocckel	203975US0X	1468

22850 7590 06/18/2004

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
KERR, KATHLEEN M	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/903,771	MOECKEL ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,10-19,37,38 and 40-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,3,4,12-15,37 and 38* is/are allowed.

6)☒ Claim(s) *10,11,18,19 and 40-51* is/are rejected.

7)☒ Claim(s) *16 and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☑ Other: fax to my

DETAILED ACTION

Application Status

1. In response to the previous Office actions, a Final rejection (mailed on January 16, 2004) and an Advisory action (mailed March 31, 2004), Applicants filed a request for continued examination (RCE) on April 8, 2004. Said RCE requested the entry of the amendment filed on March 15, 2004, previously not entered after-final as noted in the Advisory action. Said amendment cancelled Claim 5 and added new Claims 40-51. Thus, Claims 1, 3, 4, 10-19, 37-38, and 40-51 are pending in the instant Office action and will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the foreign application 10039043.9 filed in Germany on August 10, 2000; a translation of said document has been filed.

Withdrawn - Claim Objections

3. Previous objection to Claims 1 and 5 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, Claim 3, is withdrawn by virtue of Applicant's amendment and/or cancellation of said claims.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

4. Previous rejection of Claims 10-11 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "30 consecutive nucleotides of an isolated polynucleotide comprising SEQ ID NO:1" is withdrawn by virtue of Applicant's amendment.

Withdrawn - Double Patenting

5. The previous duplicate claim warning is considered moot in light of Applicant's amendments.

NEW ISSUES

Claim Objections

6. Claims 16, 17, 43, 47, and 51 are objected to for capitalizing "Coryneform". Such capitalization implies a proper name, but the term "coryneform" is a generic term of art relating to all species of *Corynebacterium*. Correction is required.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 10-11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "**consisting of at least** 30 consecutive nucleotides" (emphasis added) is unclear as to whether the language is open or closed. At their broadest (see M.P.E.P. § 2111), the claims can be interpreted as ---consisting of at least 30 consecutive nucleotides--- *attached to anything else,* which is the essence of "comprising". At their most limited, the claims might encompass ---consisting of a DNA fragment of SEQ ID NO:1 wherein said fragment consisting of at least 30 consecutive nucleotides--- which language limits to

fragments of SEQ ID NO:1 from 30 nucleotides to 1052 nucleotides (the full-length) and nothing else. If the closed interpretation is intended, the Examiner suggests the latter language.

Additionally, the clearly open language of Claim 11 ("comprising"), depending from Claim 10, perpetuates the confusion. In view of the dual interpretation of the claims, clarification is required.

8. Claims 18-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The species *B lactofermentum* and *B. divaricatum* are unclear since they are not distinct members in the Markush group, being synonyms of *C. glutamicum* (see attached Taxonomy). How their inclusion broadens the Markush group is unclear. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 40-51 are rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The concept of polynucleotides at least 70% identical (or 80% or 90%) to

SEQ ID NO:1 is not supported in the specification as originally filed. On pages 5-6, polypeptides are described with percent identity variability, but polynucleotides having a particular % identity as related to SEQ ID NO:1 are not described. Applicant is required to point out specific support (page and line number) for the amendment or to cancel the new matter.

10. Claim 10 is rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 10 is drawn to nucleic acid molecules comprising fragments of SEQ ID NO:1 in the absence of functional language; the open language ("comprising") is the broadest, reasonable claim interpretation (see above).

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification discloses a polynucleotide encoding the luxR transcriptional activator and particular fragments thereof. Applicants have fully described the genus relating to said SEQ ID NO with both sequence fragment limitations and functional limitations (i.e., having luxR activity). However, the genus of the instant claims also contains polynucleotides within the sequence fragment limitations, but having different function. Applicants have not fully described a genus that has sequence fragment limitations in the absence of functional limitations.

11. Claim 10 is rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for any polynucleotide consisting of a fragment of SEQ ID NO:1, does not reasonably provide enablement for polynucleotides comprising a part of SEQ ID NO:1 in combination with any other, even substantial sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. To make the claims to the full extent of their scope would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered

in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The instant specification describes genomic screening of the *C. glutamicum* genome. An open reading frame (ORF) is identified. It must be assumed that this ORF was named LuxR according to some similarity that was identified with known LuxR family transcriptional activators; however, no such similarity is described in the specification. No description of LuxR family proteins, even in the most generic sense, is found. No examples of other LuxR family proteins are found. Applicants present no guidance or working examples of the use of polynucleotides having only 30 consecutive nucleotides in common with SEQ ID NO:1. The nature of the invention is such that the DNA can act as a probe to identify other luxR genes; however, with such an unlimited amount and character of DNA attached to the fragment of SEQ ID NO:1 (open language), the predictability of functionality becomes extremely low. Such enormous breadth and unpredictability renders the instant claims not enabled to the full extent of their scope without undue experimentation.

12. Claims 40-51 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for any polynucleotide that encodes LuxR (SEQ ID NO:2), does not reasonably provide enablement for polynucleotides having as little as 70% identity to SEQ ID NO:1. The specification does not enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. To make the claims to the full extent of their scope would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized above.

The instant specification describes genomic screening of the *C. glutamicum* genome. An open reading frame (ORF) is identified. It must be assumed that this ORF was named LuxR according to some similarity that was identified with known LuxR family transcriptional activators; however, no such similarity is described in the specification. No description of LuxR family proteins, even in the most generic sense, is found. No examples of other LuxR family proteins are found. Applicants present no guidance or working examples of the use of polynucleotides that have such low sequence identity with respect to SEQ ID NO:1. The nature of the invention is such that the DNA encodes a functional protein, a LuxR family transcriptional activator whose attenuation enables host cells to produce more lysine; and with such a great deviation from the known sequence, the predictability of functionality becomes extremely low. Such enormous breadth and unpredictability renders the instant claims not enabled to the full extent of their scope without undue experimentation.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 40-51 are rejected under 35 U.S.C. § 102(e) as being anticipated by USPAP 2002/0197605 (Nakagawa *et al.*). The instant claims are drawn to polynucleotides, vectors, and coryneform host cells of SEQ ID NO:1. The Examiner notes that the instant claims do not have support in the priority document (or in the instant specification, see new matter rejection above).

Nakagawa *et al.* teach a 3309400 bp DNA sequence, sequence 1, a portion of which is identical to full-length SEQ ID NO:1 (see previously attached alignment to the Office action mailed December 27, 2002). Nakagawa *et al.* also teach expression vectors and host cells for the production of the encoded proteins (see Abstract).

14. Claims 40-51 are rejected under 35 U.S.C. § 102(a) as being anticipated by EP 1108790 (Nakagawa *et al.*). The instant claims are drawn to polynucleotides, vectors, and coryneform host cells of SEQ ID NO:1. The Examiner notes that the instant claims do not have support in the priority document (or in the instant specification, see new matter rejection above).

Nakagawa *et al.* teach a 309400 bp DNA sequence, sequence 7069, a portion of which is identical to full-length SEQ ID NO:1 (see previously attached alignment to the Office action mailed December 27, 2002). Nakagawa *et al.* also teach expression vectors and host cells for the production of the encoded proteins (see Abstract).

15. Claims 40-43 are rejected under 35 U.S.C. § 102(a) as being anticipated by WO 01/00842 (Pompejus *et al.*). The instant claims are drawn to polynucleotides, vectors, and coryneform host cells of a polynucleotide at least 70% identical to SEQ ID NO:1. The Examiner notes that the instant claims do not have support in the priority document (or in the instant specification, see new matter rejection above).

Pompejus *et al.* teach a 759 bp DNA sequence, sequence 297, that exactly encodes SEQ ID NO:2 (see previously attached alignment to the Office action mailed December 27, 2002); Sequence 297 is 72% identical to SEQ ID NO:1 overall. Pompejus *et al.* also teach expression vectors and host cells for the production of the encoded proteins (see Abstract).

Examiner's Comments

16. While Nakagawa *et al.* (both EP 1108790 and USPAP 2002/0197605) teach full-length SEQ ID NO:1, neither piece of art can be used as prior art with the perfection of claim language having support in the foreign priority document (filing date August 10, 2000). The Examiner further notes that the USPAP claims priority to foreign documents that *do* pre-date the foreign priority of the instant application; however, these dates cannot be used in a 102(e)-type rejection.

17. Pompejus *et al.* (WO 01/00842) does not teach full-length SEQ ID NO:1 but do teach a DNA encoding the entirety of SEQ ID NO:2. This WIPO document cannot be used as prior art with the perfection of claim language having support in the foreign priority document. However, the Examiner notes the claiming of priority to a U.S. provisional application by Pompejus *et al.*, which priority pre-dates the filing date of Applicant's foreign priority.

Summary of Pending Issues

18. The following is a summary of the issues pending in the instant application:

a) Claims 16, 17, 43, 47, and 51 stand objected to for capitalizing "Coryneform".
b) Claims 10-11 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "**consisting of at least** 30 consecutive nucleotides" (emphasis added).
c) Claims 18-19 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the species *B lactofermentum* and *B. divaricatum*.
d) Claims 40-51 stand rejected under 35 U.S.C. § 112, first paragraph, new matter.
e) Claim 10 stands rejected under 35 U.S.C. § 112, first paragraph, written description.
f) Claim 10 stands rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.
g) Claims 40-51 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.
h) Claims 40-51 stand rejected under 35 U.S.C. § 102(e) as being anticipated by USPAP 2002/0197605 (Nakagawa *et al.*).
i) Claims 40-51 stand rejected under 35 U.S.C. § 102(a) as being anticipated by EP 1108790 (Nakagawa *et al.*).
j) Claims 40-43 stand rejected under 35 U.S.C. § 102(a) as being anticipated by WO 01/00842 (Pompejus *et al.*).

Conclusion

19. Claims 1, 3, 4, 12-15, and 37-38 are allowable in the Office action; claims 10, 11, 16-19 and 40-51 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kathleen M Kerr
Examiner
Art Unit 1652

June 16, 2004